HFC-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

91888

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

September 24, 2001

WARNING LETTER
SJN-01-20

Mrs. Gail W.T. Chiang
Owner and President
Caledonian Springs, Inc.
P.O.Box 1997, Kingsill
St. Croix, USVI 00851

Dear Mrs. Chiang:

On 6/1/01, the Food and Drug Administration (FDA) conducted an inspection of your water bottling plant located at 2 F La Reine St., Saint Croix, USVI 00850. The inspectional findings and product label review revealed that your product is adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(a)(1) of the Federal Food, drug and Cosmetic Act; and in violation of Title 21, Code of Federal Regulations, Parts 129 (Processing and Bottling of Bottled Drinking Water), 165.110 (Standard of Identity for Bottled Water) and 101 (Food Labeling) as Follows:

1. The sanitation of the 5-gallon containers is inadequate. You fail to assure that the product water-contact surfaces are sanitized as required. These containers are sanitized by being exposed to hot water at a temperature of 150° F for only 3 minutes and not to a temperature of at least 170° F for at least 15 minutes or at least 200° F for at least 5 minutes. [21 CFR 129.80 (d)(2)]

2. The equipment used for 1-gallon filling operation is not suitable for its intended use. Your fitting connection is inadequate in that tape is wrapped around the holding platform designed to maintain the neck of the 1-gallon container in a fixed position. This poses a risk of contamination to the water being filled in that it does not allow an adequate cleaning and sanitation of the equipment and therefore, may represent an appropriate place for microorganisms to grow. It also provides for extra handling of the container by the operator during the filling operation. [21 CFR 129.40 (a)]

3. Failure to adequately maintain the hose used to transfer water from the transportation truck into the cistern in a manner to assure that it will not become contaminated. This hose was observed unprotected (uncapped) and exposed to the environment. This practice poses a risk of the water becoming contaminated. [21 CFR 129.37 (a)]

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Carmelo Rosa, Acting Compliance Officer.

Sincerely,

Mildred R. Barber

Mildred R. Barber
District Director